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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/340,196	06/28/1999	RYOJI KATO	990701	3596

23850 7590 05/21/2003

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/21/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/340,196

Applicant(s)

KATO ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51, 53, 54, 56, 59 and 68-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 51, 53, 54, 56, 59 and 68-77 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed Feb. 21, 2003 is acknowledged. Claim 75 has been amended.
2. Claims 51, 53, 54, 56, 59 and 68-77 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The declaration of Kenji Nakamura, filed under 37 C.F.R. 1.132, has been considered.

Claim Rejections Withdrawn:

5. The rejection of claim 75 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment removing the "and/or" language.

Claim Rejections Maintained:

6. The rejection of claims 51, 53, 54, 56, 59, 68, 69, 73, 74, and 77 under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (Yamamoto et al, Eur. J. Biochem. 143: 133-144, 1984) in view of Benita (Benita et al, Eur. J Nucl. Med., 6: 515-52-, 1981) and further in view of Canfield (WO/87/00289) is maintained for the reasons of record.

Applicant argues that claimed inventions are novel and unobvious over the prior art because the claimed methods produce unexpected results, and support this contention with a declaration. However, the data in the declaration do not appear to support a conclusion of unexpected results. Instead, the declaration is concerned with the demonstration that determining a ratio of LC bound thyroglobulin to total thyroglobulin may be used to determine malignancy, and that merely measuring LC bound thyroglobulin or total thyroglobulin cannot be used to determine malignancy. Therefore, the declaration does not appear to be directed to the unexpected nature of the invention, but, rather, to showing that measuring a ratio is better than measuring only LC bound thyroglobulin or total thyroglobulin. Since the rejection was not based on the proposition that the claims read on methods comprising only measuring LC bound thyroglobulin or total thyroglobulin, it is not clear the declaration may be used as a showing of unexpected results.

Additionally, applicant argues that the prior art does not teach or suggest how to differentiate between malignant thyroid tumors from benign thyroid tumors, but only suggests how to differentiate between malignant thyroid tumors and normal thyroid. This argument is unpersuasive, because the claims are not limited to differentiating between malignant thyroid tumors and benign thyroid tumors, and the claims include within their scope methods for differentiating between malignant thyroid tumors and normal thyroid.

7. The rejection of claims 51, 53, 54, 56, 59, 68, 69, 73, 74, and 77 under 35 U.S.C. 103(a) as being unpatentable over Tarutani (Tarutani and Ui, J. Biochem., 98: 851-857, 1985) in view of

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Benita (Benita et al, Eur. J Nucl. Med., 6: 515-52-, 1981) and further in view of Canfield (WO/87/00289) is maintained for the reasons of record.

Applicant argues that claimed inventions are novel and unobvious over the prior art because the claimed methods produce unexpected results, and support this contention with a declaration. However, the data in the declaration do not appear to support a conclusion of unexpected results. Instead, the declaration is concerned with the demonstration that determining a ratio of LC bound thyroglobulin to total thyroglobulin may be used to determine malignancy, and that merely measuring LC bound thyroglobulin or total thyroglobulin cannot be used to determine malignancy. Therefore, the declaration does not appear to be directed to the unexpected nature of the invention, but, rather, to showing that measuring a ratio is better than measuring only LC bound thyroglobulin or total thyroglobulin. Since the rejection was not based on the proposition that the claims read on methods comprising only measuring LC bound thyroglobulin or total thyroglobulin, it is not clear the declaration may be used as a showing of unexpected results.

Applicant also argues that the rejection over Tarutani, Benita and Canfield should be withdrawn because Tarutani fails to teach how to quantify the differences in ConA reactivity of different types of thyroglobulins. However, applicant fails to say what the technical hurdle is in quantifying the differences. The teachings of Canfield and Benita are relied upon for teachings of methods of quantifying thyroglobulins.

8. The rejection of claims 70-72, 75 and 77 under 35 U.S.C. 103(a) as being unpatentable over Tarutani (Tarutani and Ui, J. Biochem., 98: 851-857, 1985) or Yamamoto (Yamamoto et al,

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Eur. J. Biochem. 143: 133-144, 1984) in view of Benita (Benita et al, Eur. J Nucl. Med., 6: 515-52-, 1981) and Canfield (WO/87/00289) and further in view of Robbins (U.S. 5,902,725; issued May 11, 1999; effective filing July 3, 1996) is maintained for the reasons of record.

Applicant argues that claimed inventions are novel and unobvious over the prior art because the claimed methods produce unexpected results, and support this contention with a declaration. However, the data in the declaration do not appear to support a conclusion of unexpected results. Instead, the declaration is concerned with the demonstration that determining a ratio of LC bound thyroglobulin to total thyroglobulin may be used to determine malignancy, and that merely measuring LC bound thyroglobulin or total thyroglobulin cannot be used to determine malignancy. Therefore, the declaration does not appear to be directed to the unexpected nature of the invention, but, rather, to showing that measuring a ratio is better than measuring only LC bound thyroglobulin or total thyroglobulin. Since the rejection was not based on the proposition that the claims read on methods comprising only measuring LC bound thyroglobulin or total thyroglobulin, it is not clear the declaration may be used as a showing of unexpected results.

Applicant also argues that teachings of Robbins cannot be extrapolated to the claimed inventions because Robbins teaches a PSA assay. However, Robbins was relied upon to demonstrate that an inhibition assay is known in the art.

9. The rejection of claims 51, 53, 54, 56, 59 and 68-77 are rejected under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record. The specification, while being enabling for methods based on differential lectin binding, does not reasonably provide enablement for

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methods based on differential binding of antibodies specific for Lewis type sugar chains. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant argues that the rejection should be withdrawn because antibodies to different Lewis type sugar chains are known in the art. However, this is not the basis for the rejection. The basis for this rejection is that the specification provides no evidence that two types of thyroglobulin exist where one type has a Lewis type sugar chain and a second type lacks a Lewis type sugar chain, and that this differential glycosylation of thyroglobulin is associated with thyroid malignancy. Thus, further research to establish the relationship between the presence of Lewis type sugar chains on species of thyroglobulin and thyroid cancer would be required. Such research constitutes undue experimentation, because one of skill in the art would not have a reasonable expectation of success in establishing such a relationship. The working examples presented in the specification are not directed to methods comprising the determination of differential Lewis type sugar antigens on thyroglobulin, and the specification provides no guidance concerning the presence of Lewis type sugar antigens on thyroglobulin and any correlation with thyroid cancer. The specification provides no examples or guidance with respect to any antibodies that specifically bind to any of the Lewis type sugar chains and differential binding of these antibodies to different forms of thyroglobulin. Thus, the specification merely presents an invitation to experiment and does not provide the necessary support for the inventions as claimed.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
May 5, 2003


ANTHONY C. CAPUTA
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